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OFFICE OF
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EMERGENCY RESPONSE

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MEMORANDUM

SUBJECT: Distribution of the "Radiation Risk Assessment At CERCLA Sites: Q&A"

FROM: for Robin H. Richardson, Acting Director
Office of Superfund Remediation and Technology Innovation

TO: Superfund National Policy Managers, Regions 1–10

Purpose

The purpose of this memorandum is to transmit the final guidance "Radiation Risk Assessment At CERCLA Sites: Q&A." This new final guidance will replace a previous version of the "Radiation Risk Assessment At CERCLA Sites: Q&A" issued in 1999.

Role of the Guidance

The Office of Superfund Remediation Technology Innovation (OSRTI) developed this document to present an overview of current EPA guidance for risk assessment and related topics for radioactively contaminated Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) remedial sites. It provides answers to several commonly asked questions regarding risk assessments at radioactively contaminated CERCLA remedial sites.[1] The purpose of this document is to provide answers to commonly asked questions regarding risk assessment for radioactive contamination, describe how to analyze levels of radioactive contamination and explain how to assess the risks from radioactive

[1] The document transmitted by this memorandum provides guidance on risk assessment under CERCLA and is consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). It does not alter the NCP's general expectations for remedial actions, such as those regarding treatment of principal threat waste and the use of containment and institutional controls for low-level threat waste. Consistent with CERCLA and the NCP, remedial actions need to attain or waive Applicable or Relevant and Appropriate Requirements (ARARs); potential ARARs for contaminated ground water at radiation sites typically include Maximum Contaminant Levels (MCLs) or non-zero Maximum Contaminant Level Goals (MCLGs) established under the Safe Drinking Water Act.

This document provides guidance to U.S. Environmental Protection Agency (EPA) staff on how to conduct risk assessments for radioactively contaminated CERCLA sites. The guidance is designed to be consistent with EPA's national guidance on these issues. This guidance does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

contamination as part of a remedy for a radioactively contaminated CERCLA remedial site. This guidance is intended to help health physicists, risk assessors, remedial project managers, and others involved with risk assessment and decision making at CERCLA remedial sites with radioactive contamination.

Background

The EPA issued guidance entitled "Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination" (OSWER No. 9200.4-18, August 22, 1997). This 1997 guidance provided clarification on establishing protective cleanup levels for radioactive contamination at CERCLA sites. The guidance reiterated that cleanups of radionuclides are governed by the risk range for all carcinogens established in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) when Applicable or Relevant and Appropriate Requirements (ARARs) are not available or are not sufficiently protective. Cleanups generally should achieve a level of risk within the 10^{-4} to 10^{-6} carcinogenic risk range based on the reasonable maximum exposure for an individual. In calculating cleanup levels, one should include exposures from all potential pathways, and through all media (e.g., soil, ground water, surface water, sediment, air, structures, etc.) The guidance also provides a listing of radiation standards that are likely to be used as ARARs to establish cleanup levels or to conduct remedial actions.

The EPA previously issued "Radiation Risk Assessment At CERCLA Sites: Q&A" (OSWER No. 9200.4-31P, December 1999). The 1999 Risk Q&A provided an overview of the then current EPA guidance for risk assessment and related topics for radioactively contaminated CERCLA sites. This guidance provided answers to several commonly asked questions regarding risk assessments at radioactively contaminated CERCLA sites. In addition, it recommended that dose assessments only be conducted under CERCLA where necessary to demonstrate compliance with ARARs. Today's Risk Q&A guidance updates the 1999 version of the Risk Q&A by summarizing and citing guidance that was developed after the 1999 version. This new guidance explains how to convert radon measurements to demonstrate compliance with indoor radon standards that are potential ARARs using a methodology based on international guidance, and it changes the Superfund recommendation on what is considered a protective dose-based ARAR from 15 to 12 millirem per year (mrem/yr). The new recommendation of 12 mrem/yr regarding what dose-based ARARs are protective is based on using an updated risk assessment to achieve the same 3 x 10^{-4} cancer risk as the previous recommendation using 15 mrem/yr.

The Radiation Risk Q&A guidance is part of a continuing effort by OSRTI to provide updated guidance for addressing radioactively contaminated remedial Superfund sites consistent with our guidance for addressing chemically contaminated sites (while accounting for the technical differences between radionuclides and chemicals). OSRTI intends for this effort to facilitate remedial cleanups that are consistent with the NCP at radioactively contaminated sites and to incorporate new information based on improvements to the Superfund program.

Implementation

For questions regarding radiation site policy and guidance for CERCLA cleanup actions, readers are referred to the Superfund Radiation Webpage at http://www.epa.gov/superfund/health/contaminants/radiation/index.htm. The subject matter specialist for this guidance is Stuart Walker of OSRTI. He can be reached by e-mail at walker.stuart@epa.gov or by telephone at (703) 603-8748.

Q3. What criteria should be used to determine areas of radioactive contamination or radioactivity releases?

During the site assessment phase, Section 7 of EPA's revised Hazard Ranking System (HRS) (see Appendix A to 40 Code of Federal Regulations [CFR] Part 300) outlines the methodology for evaluating radioactive releases and determining whether a radioactive release is a high priority for the CERCLA remedial program.

During risk assessments, guidance for the measurement and evaluation of radiological contaminants is provided in the *Soil Screening Guidance for Radionuclides* (Rad SSG) documents (U.S. EPA 2000a, 2000b). The Rad SSG also provides guidance on the determination of site-specific background levels for comparison to site measurements. The Soil Screening Levels (SSLs) are not cleanup standards, but may be used to inform further investigation at sites. The SSL risk assessment equations have been superseded by those in the PRGs calculator where applicable or relevant and appropriate requirements (ARARs) are not available or sufficiently protective; therefore, the PRG calculator should be used for determining SSL risk based concentrations rather than the Rad SSG documents.

General guidance to inform the evaluation of radiological contamination is provided in the following Agency documents:

- *Methods for Evaluating the Attainment of Cleanup Standards—Volume 1: Soil and Soil Media* (U.S. EPA 1989b)
- *Statistical Methods for Evaluating the Attainment of Cleanup Standards—Volume 2: Ground Water* (U.S. EPA 1992a)
- *Statistical Methods for Evaluating the Attainment of Cleanup Standards—Volume 3: Reference-Based Standards for Soils and Solid Media* (U.S. EPA 1992b)

Although these documents do not specifically address radionuclides, most of the evaluation methods and tests provided in these documents should be applicable to both radioactive and nonradioactive contaminants.

There are two general sampling approaches for determining what is contaminated for site characterization or demonstrating compliance with cleanup levels; a not-to-exceed (NTE) or area averaging (AA) approach. In general, the same sampling approach should be used for both radionuclide and chemical contaminants in the same medium at the same site (e.g., soil, groundwater, surface water, air, or buildings) to facilitate a consistent approach for addressing radionuclides and chemicals; generally, samples for both should be collocated in the media of interest. For groundwater contamination, EPA's Superfund remedial program generally recommends an NTE approach. EPA's Superfund remedial program general practice has been to use the NTE approach for soil where residential land use is assumed. If using the AA approach, users should ensure that exposure of receptors across the exposure unit is random. However, exposure is not expected to be random under residential land use because residents often engage in activities (such as gardening or child's play) in specific portions of a yard. Under most residential situations and other non-

the extent possible, measurement data should be used to evaluate current exposures. When measurements at the exposure locations cannot be made, or when potential concentrations and exposures will be predicted at future times, modeling may be needed to estimate past or future movement of radionuclides (see Q16).

Q16. What calculation methods or multimedia radionuclide transport and exposure models are recommended by EPA for Superfund risk assessments?

A. The PRG calculators (U.S. EPA 2002a, 2007, 2009a), which are used to develop risk-based PRGs for radionuclides, are recommended by EPA for Superfund remedial radiation risk assessments. These risk and dose assessment models are similar to EPA's methods for chemical risk assessment at CERCLA sites. Guidance on how to use each calculator, the default input parameters and their sources, is provided in the user guide for each calculator. In addition, a tutorial for using the PRG calculator is included in module 3 of the on-line training course *Radiation Risk Assessment: Update and Tools* (ITRC 2007), and a tutorial for the BPRG and SPRG calculators is provided in module 3 of the on-line training course *Decontamination and Decommissioning of Radiologically-Contaminated Facilities* (ITRC 2008b). The PRG calculator superseded the *Soil Screening Guidance for Radionuclides* (Rad SSG) calculator (U.S. EPA 2000e).

To avoid unnecessary inconsistency between radiological and chemical risk assessment at the same site, users should generally use the same model for chemical and radionuclide risk assessment. If there is a reason on a site-specific basis for using another model justification for doing so should be developed. The justification should include specific supporting data and information in the administrative record. The justification normally would include the model runs using both the recommended EPA PRG model and the alternative model. Users are cautioned that they should have a thorough understanding of both the PRG recommended model and any alternative model when evaluating whether a different approach is appropriate. When alternative models are used, the user should adjust the default input parameters to be as close as possible to the PRG inputs, which may be difficult since models tend to use different definitions for parameters. Numerous computerized mathematical models have been developed by EPA and other organizations to predict the fate and transport of radionuclides in the environment; these models include single-media unsaturated zone models (for example, groundwater transport) as well as multi-media models. These models have been designed for a variety of goals, objectives, and applications; as such, no single model may be appropriate for all site-specific conditions. Generally, even when a different model is used to predict fate and transport of radionuclides through different media, EPA recommends using the PRG calculators for the remedial program to establish the risk-based concentrations to ensure consistency with CERCLA, the NCP and EPA's Superfund guidance for remedial sites.

EPA has evaluated five soil to groundwater models ranging from the simple to the multi-dimensional in *Simulating Radionuclide Fate and Transport in the Unsaturated Zone: Evaluation and Sensitivity Analyses of Select Computer Models* (EPA 2002c). This evaluation is also summarized in Part 3 of the Rad SSG *Technical Background Document*

(TBD) (EPA 2000b). For further information on selection of models appropriate to meet specific-site characteristics and requirements, readers can refer to *Ground-Water Modeling Compendium* (U.S. EPA 1994c), and *A Technical Guide to Ground-Water Model Selection at Sites Contaminated with Radioactive Substances* (U.S. EPA l994d). While these documents specifically address groundwater models, the model selection criteria and logic may be useful for other models as well.

Q17. How should Radon-222 (radon) and Radon-220 (thoron) exposures and risks be evaluated?

A. Radon-222 (Rn-222) and Radon-220 (Rn-220) are radioactive gases that are isotopes of the element radon (Rn). Each is produced by the radioactive decay of an isotope of radium (Ra). The parent radium isotope for Rn-222 (also called radon), is Ra-226 and the parent radium isotope for Rn-220 (also called thoron) is Ra-224. (Although thoron is produced from the radioactive decay of Ra-224, it is often referred to as a decay product of Ra-228, which is a longer-lived precursor typically measured in environmental samples.) Each radon isotope gives rise to a series or chain of short-lived radioactive decay products that emit alpha particles, which can damage lung tissues if inhaled. Of the two decay chains, the radon series is longer lived and more hazardous than the thoron series. Both decay chains are addressed by the same ARAR discussed below. Risk and dose assessments of radon and thoron concentrations at CERCLA remedial sites should be developed using the PRG and DCC calculators (U.S. EPA 2002a, 2004a, 2007, 2009a, 2010a, and 2010b).

Structures built on radium-contaminated soil or constructed with radium-bearing materials can accumulate elevated concentrations of radon and thoron in indoor air. Some radiation protection standards that may be potential ARARs at a site explicitly exclude dose or risk from radon and its decay products from consideration. Other potential ARARs directly address radon and its decay products (for example, under 40 CFR 192.12(b)(1) a standard of 0.03 working levels (WL) and a goal of 0.02 WL for allowable concentrations of radon decay products in indoor air).

Several EPA-approved methods are available for measuring radon and progeny concentrations in indoor air (EPA et al., Rev 1. 2000d). Because the indoor radon guidelines for homeowners are expressed in terms of picocuries per liter (pCi/L) of air, tools to address pCi/L are more prevalent than those to address WL. **For purposes of demonstrating compliance with the 0.02 WL Uranium Mill Tailings Radiation Control Act (UMTRCA) regulations as an ARAR, users may assume that either 5 pCi/L of Rn-222, or 7.5 pCi/L of Rn-220, corresponds to 0.02 WL.** Therefore 5 pCi/L of Rn-222 or 7.5 pCi/L of Rn-220 may be considered to be the concentration for complying with the UMTRCA indoor radon standard as an ARAR. These values are based on an indoor residential equilibrium fraction of 0.4 (40%) for Rn-222 and 0.02 (2%) for Rn-220. For the case of secular equilibrium, where the equilibrium fraction is 100%, the corresponding concentrations of Rn-222 and Rn-220 would be 2 pCi/L and 0.15 pCi/L respectively. The methodology for making this conversion is discussed on page 11 of the International Commission on Radiological Protection's (ICRP) guidance *Lung Cancer Risk from Radon and Progeny* (ICRP 2011). To adjust the indoor radon concentration to any given equilibrium fraction, the value for 0.02 WL at secular (100%) equilibrium is

divided by the appropriate equilibrium fraction. Thus, 2 pCi/L divided by 0.4 yields 5 pCi/L for Rn-222 and 0.15 pCi/L divided by 0.02 yields 7.5 pCi/L for Rn-220. This 40% value for Rn-222 is discussed on page 190 of the NAS Report *Health Effects of Exposure to Radon: BEIR VI* (NAS 1999). For Rn-220, the assumed equilibrium factor of 2% is discussed on page 206 of *Appendix E: Sources-to-effects assessment for radon in homes and workplaces* of the United Nations Report *Effects of Ionizing Radiation Volume II* (UNSCEAR 2006).

Computer codes have been developed to predict radon concentrations in indoor air and potential human exposure, based on simplified equations and assumptions; these models may yield results that are meaningful on average (e.g., for a geographical region) but highly imprecise for an individual house or structure. Despite their widespread use, these codes should be used with caution and their estimates interpreted carefully. Also, some states have their own radon testing and mitigation requirements that may be potential ARARs at a site (see Q38).

Q18. How long a time period should be considered for possible future exposures?

A. The PRG calculators include assumptions for the appropriate time period for generic land use exposure scenarios. Furthermore, in some cases, federal or state ARARs may include specific time-frame requirements for a given purpose, which is often a thousand years for dose-based standards. Several of the isotopes are listed with a "+E" designation. This designation indicates that the dose conversion factor (DCF) includes the contribution from ingrowth of daughter isotopes out to 1,000 years. As a result, the DCC calculators allow the selection of radionuclides with the +E designation, which provide a dose assessment based on the year of peak dose over 1,000 years since many standards that are potential ARARs specify this time-period for dose assessments. If the ARAR does not specify a time-period for assessment, users should use the +D designation for a radionuclide where the decay chain is in secular equilibrium. The +D designation indicates the contribution from ingrowth of daughter isotopes out to 100 years.

Q19. How should the results of the exposure assessment for radionuclides be presented?

A. Results of the exposure assessment for radionuclides should be presented with intake and external exposure estimates for use in risk characterization. If it is determined that there are dose-based standards that are ARARs at a CERCLA remedial site, then the intake and external exposure estimates should also be used for dose assessment.

Note that intake estimates for radionuclides should not be divided by body weight or averaging time as is done for chemical contaminants, because the radionuclide slope factors and dose conversion factors are age averaged, which accounts for average body weight in the United States population over different ages and the risk or dose is dependent upon the total exposure not the time period over which it occurs. Intake estimates for inhalation or ingestion pathways should include the total activity of each radionuclide inhaled or ingested via each pertinent route of exposure (e.g., ingestion of

contaminated drinking water, direct ingestion of contaminated soil, ingestion of contaminated produce, milk, or meat). Measured or predicted external exposure rates should be presented, along with the exposure time, frequency, and duration. The concentration of each radionuclide in the medium is needed to estimate the risk from the external pathway using slope factors.

III. TOXICITY ASSESSMENT

Q20. What is the mechanism of radiation damage?

A. Radiation emitted by radioactive substances can transfer sufficient localized energy to atoms to remove electrons from the electron cloud surrounding the nucleus (ionization). In living tissue, this energy transfer can produce chemically reactive ions or free radicals, destroy cellular constituents, and damage DNA. Improperly repaired DNA damage is thought to be a major factor in carcinogenesis. (While ionizing radiation may also cause other detrimental health impacts, only radiogenic cancer risk is normally considered in CERCLA risk assessments [see Q26].)

The type of ionizing radiation emitted by a particular radionuclide depends on the exact nature of the nuclear transformation, and may include emission of alpha particles, beta particles (electrons or positrons), and neutrons; each of these transformations may be accompanied by emission of photons (gamma radiation or X-rays). Each type of radiation differs in its physical characteristics and in its ability to inflict damage to biological tissue. The various types of radiation are often categorized as low linear energy transfer (LET) radiation (photons and electrons) and high-LET radiations (alpha particles and neutrons) for radiation risk and dose estimates.

Ionizing radiation can cause deleterious effects on biological tissues only when the energy released during radioactive decay is absorbed in tissue. The average energy imparted by ionizing radiation per unit mass of tissue is called the "absorbed dose." The SI unit of absorbed dose is the joule per kilogram, also assigned the special name the Gray (1 Gy = 1 joule/kg); the conventional unit of absorbed dose is the rad (1 rad = 100 ergs/g = 0.01 Gy).

Q21. What are radionuclide slope factors?

A. EPA has developed slope factors for estimating incremental cancer risks resulting from exposure to radionuclides via inhalation, ingestion, and external exposure pathways. Slope factors for radionuclides represent the probability of cancer incidence as a result of a unit exposure to a given radionuclide averaged over a lifetime using the linear no-threshold model. It is the age-averaged lifetime excess cancer incident rate per unit intake (or unit exposure for external exposure pathway) of a radionuclide (U.S. EPA 1989a).

EPA recommends the slope factors that are used in the PRG calculators for CERCLA remedial radiation risk estimates (U.S. EPA 2002a, 2007, and 2009a). Current radionuclide slope factors incorporate the age- and gender-specific radiogenic cancer risk models from *Federal Guidance Report No. 13: Cancer Risk Coefficients for*

Environmental Exposure to Radionuclides (U.S. EPA 1999c), which assume a maximum lifetime for an individual of 120 years, but incorporate competing causes of death over a 120 year lifetime.

Q22. What are radionuclide dose conversion factors?

A. Dose conversion factors (DCFs), or "dose coefficients", for a given radionuclide represent the dose equivalent per unit intake (i.e., ingestion or inhalation) or external exposure of that radionuclide. These DCFs are used to convert the amount of radionuclide externally exposed, ingested, or inhaled to a radiation dose from an environmental sample of modeled estimate of radionuclide concentration in soil, air, water, or foodstuffs. DCFs may be specified for specific body organs or tissues of interest, or as a weighted sum of individual organ dose, termed the effective dose equivalent. (These quantities are discussed further in Q23.) These DCFs may be multiplied by the total activity of each radionuclide inhaled or ingested per year, or the external exposure concentration to which a receptor may be exposed, to estimate the dose equivalent to the receptor.

EPA recommends the DCFs that are used in the DCC calculators for CERCLA remedial dose assessments (U.S. EPA 2004a, 2010a, and 2010b). The most up to date radionuclide DCFs in the current DCC calculators, ICRP 60, incorporate age- and gender-specific models and are from the CD supplement to *Federal Guidance Report No. 13: Cancer Risk Coefficients for Environmental Exposure to Radionuclides* (U.S. EPA 1999c).

Q23. What is dose equivalent, effective dose equivalent, and related quantities?

A. As discussed in Q20, different types of radiation have differing effectiveness in transferring their energy to living tissue. Since it is often desirable to compare doses from different types of radiation, the quantity "dose equivalent," or "equivalent dose," has been defined as a measure of the energy absorbed by living tissues, adjusted for the type of radiation present. The SI unit for dose equivalent is the Sievert (Sv) and the conventional unit is the rem (1 rem = 0.01 Sv). The absorbed dose is multiplied by Quality Factor (Q) or radiation weighting factor (w_R) to compute dose equivalent; these values range from 1 for photons and electrons to 10 for neutrons to 20 for alpha particles. For an equal amount of energy absorbed, an alpha particle will inflict approximately 20 times more damage to biological tissue than that inflicted by a beta particle or gamma ray. Internally deposited (inhaled or ingested) radionuclides may be deposited in various organs and tissues long after initial deposition. The "committed dose equivalent" is defined as the integrated dose equivalent that will be received by an individual during a 50-year period following the intake. By contrast, external radiation exposure contributes to dose only as long as the receptor is present within the external radiation field.

When they are exposed to equal doses of radiation, different organs and tissues in the human body will exhibit different cancer induction rates. The quantity "effective dose equivalent," or "effective dose," was developed by the International Commission on Radiological Protection (ICRP) to account for these differences and to normalize radiation

doses and effects on a whole body basis for regulation of occupational exposure. The effective dose equivalent is computed as a weighted sum of organ-specific dose equivalent values, with weighting factors specified by the ICRP (ICRP 1977, 1979). The effective dose equivalent is equal to that dose equivalent, delivered at a uniform whole-body rate, that corresponds to the same number (but possibly dissimilar distribution) of fatal stochastic health effects as the particular combination of organ dose equivalents.

Q24. What is the critical organ approach to dose limitation?

A. Regulatory standards developed by EPA and the Nuclear Regulatory Commission (NRC) that use the critical organ approach usually consist of a combination of whole body and critical organ dose limits, such as 25 mrem/yr to the whole body, 75 mrem/yr to the thyroid, and 25 mrem/yr to any critical organ other than the thyroid. For example, EPA's uranium fuel cycle rule, 40 CFR 190.10(a); NRC's low level waste rule, 10 CFR 61.41; and EPA's management and storage of high level waste by NRC and agreement states rule, 40 CFR 191.03(a), use this "25/75/25 mrem/yr" dose limit approach. EPA's management and storage of high level waste by U.S. Department of Energy (DOE) rule, 40 CFR 191.03(b), is expressed as 25 mrem/yr to the whole body and 75 mrem/yr to any critical organ (including the thyroid). When these standards were adopted, dose was calculated and controlled for each organ in the body and uniform radiation of the "whole body." The "critical organ" was the organ that received the most dose for the radionuclide concerned. With the adoption of the dose equivalent concept, the dose to each organ is weighted according to the effect of the radiation on the overall system (person). The new dose system for the EPA and NRC regulations allows for one value of dose equivalent (see Q 23) to be assigned as a limit, which is protective of the entire system. The critical organ approach required individual limits for each organ based on the effect of radiation on that organ.

It should be noted that although most critical organ standards include 25 mrem/yr or higher (for example, 75 mrem/yr to the thyroid) dose limits, these critical organ standards are not comparable to 25 mrem/yr effective dose equivalent standards or guidance. EPA has determined that for Superfund remedial sites a 25 mrem/yr effective dose equivalent level should not be used for the purposes of establishing cleanup levels at CERCLA remedial sites (see 1997a). This determination does not apply to critical organ standards (see 1997a). For further discussion of EPA's comparison of critical organ and effective dose equivalent limits see pages 4-5 of Attachment B to EPA 1997a. The DCC, BDCC, and SDCC calculators are not intended for demonstrating compliance with ARARs using the critical organ dose approach based on ICRP 2.

Q25. How should radionuclide slope factors and dose conversion factors be used?

A. **EPA recommends that radionuclide slope factors be used to estimate the excess cancer risk resulting from exposure to radionuclides at radiologically contaminated sites, consistent with the NCP's risk range (10^{-4} to 10^{-6} lifetime excess cancer risk) for CERCLA remedial responses.** The incremental risk generally is calculated by multiplying the estimates of chronic daily intake over a lifetime by a

slope factor that is appropriate for the exposure route (ingestion, inhalation and external exposure) and media (e.g., soil, food and water) of concern.

Cancer risk from radionuclide exposures may also be estimated by multiplying the effective dose equivalent computed using the dose conversion factors (DCFs) by a risk-per-dose factor. Some key differences in the two cancer risk methods are summarized in Table 2.

The primary use of DCFs by the Superfund remedial program generally should be to compute doses resulting from site-related exposures for comparison with radiation protection standards (see Q32 and 33) that are determined to be ARARs. This can be accurately accomplished by multiplying the estimates of annual chronic daily intake by a dose conversion factor that is appropriate for the exposure route (ingestion, inhalation and external exposure) and media (e.g., soil, food and water) of concern.

At Superfund remedial responses, excess cancer risk generally represents cumulative lifetime cancer morbidity risk from a multi-year exposure period (e.g., 30 years of exposure for residential scenario). In contrast, when complying with most dose-based standards that are considered to be ARARs at CERCLA remedial responses, the dose limits are typically expressed in terms of annual exposure (for example, the effective dose equivalent resulting from exposure during a 1-year period, mrem/year).

DCFs from the default settings in the latest versions of the DCC, BDCC, and SDCC calculators (U.S. EPA 2004a, 2010a, and 2010b) should be used for complying with ARARs based on effective dose equivalent, while DCFs from ICRP 2 should be used when complying with ARARs based on the critical organ approach. There are some potential ARARs (for example, the maximum contaminant levels [MCLs] for beta and photon emitters) that specify in the text of the regulation itself which DCFs should be used.

Q26. In addition to cancer, should the potential teratogenic and genetic effects of radiation exposures be considered?

A. Biological effects associated with exposure to ionizing radiation in the environment may include carcinogenicity (induction of cancer), mutagenicity (induction of mutations in somatic or reproductive cells, including genetic effects), and teratogenicity (effects on the growth and development of an embryo or fetus). Agency guidance (U.S. EPA 1989a, 1994b) indicates that the radiogenic cancer risk is normally assumed to be limiting for risk assessments at Superfund remedial sites, and evaluation of teratogenic and genetic effects is not required. Similarly, consideration of acute effects at CERCLA remedial sites generally is not required, since these effects occur only at doses much higher than those normally associated with environmental exposures.

Table 2. Comparison of Radiation Risk Estimation Methodologies: Slope Factors vs. Effective Dose Equivalent

Parameter	Slope Factor Approach	Effective Dose Equivalent (EDE) x Risk Factor Approach
Competing Risks	• Persons dying from competing causes of death (such as disease, accidents) are not considered susceptible to radiogenic cancer. • Probability of dying at a particular age from competing risks is considered based on the mortality rate from all causes at that age in the 1989 to 1991 (previously 1979 to 1981) U.S. population.	• Competing risks not considered.
Risk Models	• Age-dependent and gender-dependent risk models for 14 cancer sites are considered individually and integrated into the slope factor estimate.	• Risk estimate averaged over all ages, sexes, and cancer sites.
Genetic Risk	• Genetic risk is not considered in the slope factor estimates; however, ovary is considered as a potential cancer site.	• EDE value includes genetic risk component.
Dose Estimates	• Low-LET and high-LET dose estimates considered separately for each target organ.	Dose-equivalent includes both low-LET and high-LET radiation, multiplied by appropriate Quality Factors.
RBE for high- LET (alpha) radiation	• 20 for most sites (8 prior to 1994) • 10 for breast (8 prior to 1994) • 1 for leukemia (1.117 prior to 1994)	• 20 (all sites)
Organs Considered	• Estimates of absorbed dose to 16 target organs/tissues considered for 13 specific cancer sites plus residual cancers.	• EDE (ICRP, 1979) considers dose estimates to six specific target organs plus remainder (weighted average of five other organs).
Lung Dose Definition	• Absorbed dose used to estimate lung cancer risk computed as weighted sum of dose to tracheobronchial region (80%) and pulmonary lung (20%).	• Average dose to total lung (mass weighted sum of doses to the tracheobronchial region, pulmonary region, and pulmonary lymph nodes).
Integration Period	• Variable length (depending on organ-specific risk models and consideration of competing risks) not to exceed 110 years.	• Fixed integration period of 50 years typically considered.
Dosimetric / Metabolic Models	• Metabolic models and parameters for dose estimates follow recent recommendations of the ICRP series of documents on age-specific dosimetry (ICRP, 1989, 1993, 1995a, 1995b), where available; previous estimates based primarily on ICRP 30 (ICRP, 1979).	• Typically employ ICRP Publication 30 (ICRP 1979) models and parameter for radionuclide uptake, distribution, and retention.

Q27. Should chemical toxicity of radionuclides be considered?

A. At Superfund remedial program radiation sites, EPA generally evaluates potential human health risks based on the radiotoxicity (the adverse health effects caused by ionizing radiation), rather than on the chemical toxicity, of each radionuclide present. Uranium, in soluble form, is a kidney toxin at mass concentrations slightly above background levels. It is the only radionuclide for which the chemical toxicity has been identified to be comparable to or greater than the radiotoxicity and for which an oral reference dose (RfD) has been established to evaluate chemical toxicity. To properly evaluate human health risks, both effects (radiogenic cancer risk and chemical toxicity) should be considered for radioisotopes of uranium. When risk estimates will be made of the chemical toxicity of uranium, EPA recommends using the *Regional Screening Levels for Chemical Contaminants at Superfund Sites* (RSL) calculator (U.S. EPA 2008) for uranium in soil, water and air and the equations in (U.S. EPA 2003) for uranium in dust inside of buildings. The RSL calculator is frequently updated.

IV. RISK CHARACTERIZATION

Q28. How should radionuclide risks be estimated?

A. At Superfund remedial sites, risks from radionuclide exposures should be estimated in a manner analogous to that used for chemical contaminants. The estimates of intake by inhalation and ingestion and the external exposure over the period of exposure estimated for the land use (e.g., 30 years residential, 25 years commercial/industrial) from the exposure assessment should be coupled with the appropriate slope factors for each radionuclide and exposure pathway. Only excess cancer risk should be considered for most radionuclides (except for uranium, as discussed in Q27). The total incremental lifetime cancer risk attributed to radiation exposure is estimated as the sum of the risks from all radionuclides in all exposure pathways.

Q29. Should radionuclide and chemical risks be combined?

A. Generally, yes. At CERCLA remedial sites, excess cancer risk from both radionuclides and chemical carcinogens should be summed to provide an estimate of the combined risk presented by all carcinogenic contaminants as specified in OSWER directive 9200.4-18 (U.S. EPA 1997a). An exception would be cases in which a person reasonably cannot be exposed to both chemical and radiological carcinogens; Regions should include specific supporting data and information in the administrative record to document this conclusion. Similarly, the chemical toxicity from uranium should be combined as appropriate with that of other site-related contaminants. As recommended in *RAGS* Part A (U.S. EPA 1989a), risk estimates for radionuclides and chemical contaminants also should be tabulated and presented separately in the risk characterization report.

There are generally several differences between slope factors for radionuclides and chemicals. However, similar differences also occur between different chemical slope factors. **In the absence of additional information, it is reasonable to assume that**

excess cancer risks are additive for evaluating the total incremental cancer risk associated with a contaminated site.

Q30. How should risk characterization results for radionuclides be presented?

A. Results should be presented according to the standardized reporting format presented in *RAGS* Part D (U.S. EPA 1998a). EPA guidance for risk characterization (U.S. EPA 1995a, 1995b) indicates that four descriptors of risk are generally needed for a full characterization of risk: (1) central tendency (such as median, mean) estimate of individual risk; (2) high-end estimate (for example, the 95th percentile) of individual risk; (3) risk to important subgroups of the population, such as highly exposed or highly susceptible groups (such as children) or individuals, if known; and (4) population risk. The reasonable maximum exposure (RME) estimate of individual risk typically presented in Superfund risk assessments represents a measure of the high-end individual exposure and risk. While the RME estimate remains the primary scenario for Superfund risk management decisions, additional risk descriptors may be included to describe site risks more thoroughly (e.g., central tendency, sensitive subpopulations). Population risk is generally not used as part of Superfund risk assessments.

Q31. Is it necessary to present the collective risk to populations estimated along with that to individual receptors?

A. Generally, no. Risk to potential RME individual receptors generally is the primary measure of protectiveness under the CERCLA remedial process (the target range of 10^{-6} to 10^{-4} lifetime excess cancer risk to the RME receptor). As noted in Q30, however, Agency guidance (U.S. EPA 1995a, 1995b) also indicates that the central tendency risk to the potentially exposed population may be evaluated where possible. Consideration of central tendency risk may provide additional input to risk management decisions; such considerations may be either qualitative or quantitative, depending on the availability of data.

Q32. How should uncertainty in estimates of radiation risk be addressed in the risk characterization report?

A. Consideration of uncertainty in estimates of risks from potential exposure to radioactive materials at CERCLA sites typically is an essential element of informed risk management decisions. *RAGS* and subsequent guidance (U.S. EPA 1995a, 1995b) stress the importance of a thorough presentation of the uncertainties, limitations, and assumptions that underlie estimates of risk. Either qualitative or quantitative evaluation may be appropriate, depending on the availability of data and the magnitude of predicted risk. In either case, the evaluation should address both uncertainty ("the lack of knowledge about specific factors, parameters, or models") and variability ("observed differences attributable to true heterogeneity or diversity in a population or exposure parameter"). Estimates of potential risk should include both central tendency estimates (median, mean) and high-end estimates (such as RME or 95th percentile).

Extrapolation from high dose and dose rate exposure is generally done to estimate risks of low-level exposures for both chemical carcinogens and radionuclides. This extrapolation typically constitutes the greatest source of uncertainty. Additional uncertainty may be introduced due to extrapolation of animal data to humans for chemical carcinogens. Slope factors for both radionuclides and chemicals are used to estimate incremental cancer risk, which typically represents a small increment over a relatively high baseline incidence. It should be noted that there is less uncertainty associated with the slope factors for radionuclides than any, or almost any, chemical slope factors since the radionuclide slope factors are based primarily on human rather than animal data. Other sources of uncertainty may be associated with instrumentation and measurements used to characterize the nature and extent of radionuclides of concern, and the parameters used to characterize potential exposures of current and future receptors (such as intake rates and frequency of exposure).

Probabilistic Risk Assessment (PRA) may be used to provide quantitative estimates of the uncertainties in the risk assessment. However, probabilistic estimates of risk should be presented as a supplement to, not instead of, the deterministic (point estimate) methods outlined in *RAGS* Part A. A tiered approach is often useful, with the rigor of the analysis depending on the magnitude of predicted risk. Factors to be considered in conducting a probabilistic analysis typically should include the sensitivity of parameters, the correlation or dependencies between parameters, and the distributions of parameter values and model estimates. Detailed guidance on this topic is provided in *Use of Probabilistic Techniques (Including Monte Carlo Analysis) in Risk Assessment* (U.S. EPA 1997c) and *Guiding Principles for Monte Carlo Analysis* (U.S. EPA 1997d).

Q33. When should a dose assessment be performed?

A. Dose assessments should be conducted during CERCLA remedial responses only when considering compliance of clean up plans with dose-based ARARs. As discussed in OSWER Directive 9200.4-18 (U.S. EPA 1997a), cleanup levels for radioactive contamination at remedial sites should be established as they would for any chemical that poses an unacceptable risk and the risks should be characterized in standard Agency risk language consistent with CERCLA guidance for remedial sites. Thus, **cleanup levels not based on an ARAR should be based on the carcinogenic risk range (generally 10^{-4} to 10^{-6}, with 10^{-6} as the point of departure and 1 x 10^{-6} used for PRGs) and expressed in terms of risk (# x $10^{-\#}$).**

Q34. What is the upper end of the risk range with respect to radionuclides?

A. Consistent with existing Agency guidance for the CERCLA remedial program, while the upper end of the risk range is not a discrete line at 1 x 10^{-4}, EPA generally uses 1 x 10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable based on site-specific circumstances. For further discussion of these points and how EPA uses the risk range, see OSWER Directive 9355.0-30, *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (U.S. EPA 1991d). In general, dose assessment used as a method to assess risk is not recommended as a way of ensuring protectiveness of human health at CERCLA remedial sites.

Q35. Should the ARAR protectiveness criteria evaluation recommendation be changed from 15 mrem/yr to reflect the updates to radiation risk estimates contained in Federal Guidance Report 13?

A. **Yes, ARAR protectiveness criteria evaluation recommendation of 15 mrem/yr should be changed to 12 mrem/yr to reflect the current federal government position on the risks posed by radiation, which is contained in EPA's Federal Guidance Report 13 (U.S. EPA 1999c)**. More recent scientific information reflected in EPA's Federal Guidance Report 13 risk estimates show that 12 mrem/yr is now considered to correspond approximately to 3 x 10^{-4} excess lifetime cancer risk. This *updated approach is based on FGR 13's assumption of a risk of cancer incidence* of 8.46 x 10^{-4} per rem of exposure (while still using the EPA CERCLA standard period of exposure of 30 years for residential land use, which also was the basis of the 15 mrem/yr determination in OSWER Directive 9200.4-18). Therefore, the ARAR evaluation guidance first discussed in OSWER Directive 9200.4-18 is being updated to 12 mrem/yr so that ARARs that are greater than 12 mrem/yr effective dose equivalent (EDE) are generally not considered sufficiently protective for developing cleanup levels under CERCLA at remedial sites. As before, this ARAR evaluation tool should not be used as a to be considered (TBC) as a basis for establishing 12 mrem/yr cleanup levels at CERCLA remedial sites.

Please note that the prior references to 15 mrem/yr in OSWER Directive 9200.4-18 were intended as guidance for the evaluation of potential ARARs and TBCs factors and **should not be used as a TBC for establishing 15 mrem/yr cleanup levels at CERCLA sites**. Consistent with that guidance, using 15 mrem/yr as an ARAR evaluation tool originally was based on three factors:

1. The CERCLA risk range for remedial sites. In 1997, 15 mrem/yr was estimated to correspond to approximately 3 x 10^{-4} under the then EPA practice of using the dose to risk estimate conversions assumption of a risk of cancer incidence of 7.6 x 10^{-4} per rem of exposure, found in ICRP 1991 and NAS 1990. This dose to risk estimate has been superseded by the assumption of a risk of cancer incidence of 8.46 x 10^{-4} per rem of exposure in FGR 13 (U.S. EPA 1999c).
2. Prior EPA radiation rulemakings, and
3. Prior EPA CERCLA site-specific decisions.

Q36. Should dose recommendations from other federal agencies be used to assess risk or establish cleanup levels?

A. Generally, no. **Dose assessments generally should only be performed to assess risks or to establish cleanup levels at CERCLA remedial sites** to show compliance with an ARAR that requires a dose assessment (for example 40 CFR 61 Subparts H and I, and 10 CFR 61.41). Dose level recommendations from international and other non-EPA organizations are not enforceable and therefore cannot be ARARs. The selection of cleanup levels for carcinogens for CERCLA remedy selection purposes should be consistent with the NCP and CERCLA guidance – i.e., based on the risk range when

ARARs are not available or are not sufficiently protective. EPA has made the policy decision to use the NCP's risk range in developing cleanup levels for radionuclides at CERCLA remedial sites rather than using dose-based guidance since the use of dose-based guidance. See Q10 for more information on this determination.

EPA recommends using the DCC, BDCC, and SDCC calculators (U.S. EPA 2004a, 2010a, and 2010b) to develop dose assessments for ARAR compliance purposes at Superfund remedial sites. As indicated on page 2 of the memorandum transmitting the DCC calculator (U.S. EPA 2004c), that guidance superseded the dose assessment equations in Chapter 10 of *RAGs* Part A (U.S. EPA 1989a).

Q37. How and when should exposure rate be used to estimate radionuclide risks?

A. **As discussed previously (see Q25 and Q28), EPA recommends that estimates of radiation risk should be derived using slope factors, in a manner analogous to that used for chemical contaminants.** However, to ensure protectiveness of human health consistent with CERCLA and the NCP requirements for the remedial program, there may be circumstances where it is desirable at CERCLA remedial sites to also consider estimates of risk based on direct exposure rate measurements of penetrating radiation in addition to risk estimates based on slope factors. Examples of such circumstances where it may be appropriate to also use direct measurements for assessing risk from external exposure to penetrating radiation include:

- During early site assessment efforts when the site manager is attempting to communicate the relative risk posed by areas containing elevated levels of radiation,

- As a real-time method for indicating that remedial objectives are being met during the conduct of the response action. The use of exposure rate measurements during the conduct of the response actions should not decrease the need for a final status survey.

To facilitate developing risk estimates under any of these situations, EPA is developing a Counts Per Minute (CPM) calculator (U.S. EPA 2014a) to model correlations in exposure rate measurements back to modeled estimates of cancer risk. Direct radiation exposure rate measurements may provide important indications of radiation risks at a site, particularly during early investigations, when these may be the first data available. However, these data may reflect only a subset of the radionuclides and exposure pathways of potential concern (for example, only external exposure from gamma-emitting radionuclides in near-surface soil), and may present an incomplete picture of site risks (such as risk from internal exposures, or potential increased future risks from radionuclides in subsurface soils). In most cases, more accurate estimation of radiation risks will require additional site characterization data, including concentrations of all radionuclides of concern in all pertinent environmental media. The principal benefit of using direct exposure rate measurements is the speed and convenience of analysis, and reducing the potential for missing areas of contamination. **However, exposure rate data generally should be used in conjunction with characterization data of radionuclides concentrations**